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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0945-0003-60D]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945-0003 -60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, Sherrette.funn@hhs.gov, or call 202-795-7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use

of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR Parts 160 and 164

Type of Collection: Extension

OMB No. 0945-0003 – Office for Civil Rights (OCR) – Health Information Privacy Division

Abstract: Office for Civil Rights (OCR) requests approval to extend this existing, approved collection without changing any collecting requirements while OCR obtains public comment through a Notice of Proposed Rulemaking (NPRM) proposing modifications to the HIPAA Rules that will affect the hourly burdens associated with the Rules. When the NPRM is published, we expect to receive robust public comment on existing burdens associated with compliance with the HIPAA Rules and on changes in burden that could result from the modifications proposed in the NPRM. OCR will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

Likely Respondents: HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

Estimated Annualized Burden Hour Table

Forms (If necessary)	Respondents (If necessary)	Number of Respondents	Number of Responses per Respondents	Average Burden per Response	Total Burden Hours
45 CFR 160.204 Process for Requesting Exception Determinations (states or persons)	A state's chief elected official or designee	1	1	16	16
45 CFR 164.308 Risk Analysis - Documentation	Covered entities; business associates	1,700,000	1	10	17,000,000

45 CFR 164.308 Information System Activity Review – Documentation	Covered entities; business associates	1,700,000	12	0.75	15,300,000
45 CFR 164.308 Security Reminders – Periodic Updates	Covered entities; business associates	1,700,000	12	1	20,400,000
45 CFR 164.308 Security Incidents (other than breaches) – Documentation	Covered entities; business associates	1,700,000	52	5	442,000,000
45 CFR 164.308 Contingency Plan – Testing and Revision	Covered entities; business associates	1,700,000	1	8	13,600,000
45 CFR 164.308 Contingency Plan – Criticality Analysis	Covered entities; business associates	1,700,000	1	4	6,800,000
45 CFR 164.310 Maintenance Records	Covered entities; business associates	1,700,000	12	6	122,400,000
45 CFR 164.314 Security Incidents – Business Associate reporting of incidents (other than breach) to Covered Entities	Business associates	1,000,000	12	20	240,000,000
45 CFR 164.316 Documentation – Review and Update	Covered entities; business associates	1,700,000	1	6	10,200,000
45 CFR 164.404 Individual Notice— Written and E-mail Notice (drafting)	Covered entities	58,481	1	0.5	29,241
45 CFR 164.404 Individual Notice— Written and E-mail	Covered entities	58,481	1	0.5	29,241

Notice (preparing and documenting notification)					
45 CFR 164.404 Individual Notice— Written and E-mail Notice (processing and sending)	Covered entities	58,481	353	0.008	165,150
45 CFR 164.404 Individual Notice— Substitute Notice (posting or publishing)	Covered entities	2,746	1	1	2,746
45 CFR 164.404 Individual Notice— Substitute Notice (staffing toll-free number)	Covered entities	2,746	1	5.75	15,790
45 CFR 164.404 Individual Notice— Substitute Notice (individuals’ voluntary burden to call toll-free number for information)	Covered entities	11,326,440	1	0.125	1,415,805
45 CFR 164.406 Media Notice	Covered entities	267	1	1.25	334
45 CFR 164.408 Notice to Secretary (notice for breaches affecting 500 or more individuals)	Covered entities	267	1	1.25	334
45 CFR 164.408 Notice to Secretary (notice for breaches affecting <500 individuals)	Covered entities	58,215	1	1	58,215
45 CFR 164.410 Business associate notice to covered entity – 500 or more Affected Individuals	Business associates	20	1	50	1,000

45 CFR 164.410 Business associate notice to covered entity – Less than 500 Affected Individuals	Business associates	1,165	1	8	9,320
45 CFR 164.414 500 or More Affected Individuals (investigating and documenting breach)	Covered entities	267	1	50	13,350
45 CFR 164.414 Less than 500 Affected Individuals (investigating and documenting breach) -- affecting 10-499	Covered entities	2,479	1	8	19,832
45 CFR 164.414 Less than 500 Affected Individuals (investigating and documenting breach) -- affecting <10	Covered entities	55,736	1	4	222,944
45 CFR 164.504 Uses and Disclosures – Organizational Requirements	Covered entities	700,000	1	0.083333333	58,333
45 CFR 164.508 Uses and Disclosures for Which Individual authorization is required	Covered entities	700,000	1	1	700,000
45 CFR 164.512 Uses and Disclosures for Research Purposes	Covered entities	113,524	1	0.083333333	9,460
45 CFR 164.520 Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by paper mail)	Covered entities – health plans	100,000,000	1	0.004166667	416,667

45 CFR 164.520 Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by electronic mail)	Covered entities – health plans	100,000,000	1	0.002783333	278,333
45 CFR 164.520 Notice of Privacy Practices for Protected Health Information (health care providers – dissemination and acknowledgement)	Covered entities – health care providers	613,000,000	1	0.5	30,650,000
45 CFR 164.522 Rights to Request Privacy Protection for Protected Health Information	Covered entities – health care providers, health plans	20,000	1	0.5	1,000
45 CFR 164.524 Access of Individuals to Protected Health Information (disclosures)	Covered entities – health care providers, health plans, clearinghouses	200,000	1	0.5	10,000
45 CFR 164.526 Amendment of Protected Health Information (requests)	Covered entities - health care providers, health plans, clearinghouses	150,000	1	0.083333333	12,500
45 CFR 164.526 Amendment of Protected Health Information (denials)	Covered entities - health care providers, health plans, clearinghouses	50,000	1	0.083333333	4,167
45 CFR 164.528 Accounting for Disclosures of Protected Health Information	Covered entities - health care providers, health plans, clearinghouses	5,000	1	0.05	250
TOTAL					921,824,027

TERRY CLARK

Office of the Secretary

Paperwork Reduction Act Reports Clearance Officer

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